REMARKS/ARGUMENTS

Claims 20-34 remain in this application. Claims 1-19 have been canceled.

Claim 20 has been amended. Support for the addition of solid can be found on page 1, line 7 and page 21, line 26 et seq. The removal of "in the subject" was to clarify the claimed invention. Controlled release is described in the application more specifically on pages 5 and 6. Controlled release can be demonstrated by in vivo or by in vitro testing. Applicants' attorney respectfully submits that these amendments do not introduce new matter. Applicants' attorney therefore respectfully requests entry of these amendments.

Claim 20 has been rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. This rejection is based on the term "viscous" being viewed as indefinite. However applicants respectfully requests reconsideration and withdrawal of this rejection.

The viscosity parameters for the hydrophilic polymers of the present invention are provided on page 11, lines 19 et seq. Applicants' attorney therefore respectfully submits that one of ordinary skill in the art upon reading this passage would understand the range of viscosity that is encompassed by claim 20. Accordingly, applicants' attorney respectfully requests reconsideration and withdrawal of the rejection of claim 20.

The rejection of claims 20-22, 25 and 32-34 under 35 U.S.C. 102(b) as being anticipated by Francois et al. (WO 97/44039) has been reviewed. However, in view of the following remarks and amendment of claim 20 this rejection is submitted to be in error.

Francois et al. (WO 97/44039) is considered to be a significant contribution to the art in the formulation of an injectable, aqueous suspensions of 9-hydroxyrisperidone fatty acid esters for depot formulations. However, the present invention is patentably distinguishable from Francois et al.

The present invention is directed to hydrophilic controlled release formulations. The formulations are indicated in the specifications to be solid formulations, which are preferably used in solid oral dosage forms. Applicants' attorney notes that the specification does provide for intermediate mixing steps where liquid mixtures may be used as intermediates that are dried or where the liquid is evaporated away. However, the formulations as described in the specifications would be understood by one of ordinary skill in the art to be solid formulations as powdery or solid matrix that is formed into a solid oral dosage form (e.g. tablets, capsules and the like). To clarify this point applicants' attorney has added the word "solid" to the claim. Therefore, applicants' attorney respectfully submits that the aqueous injectable suspension of Francois et al. does not anticipate the present invention. In view of these comments, applicants respectfully request reconsideration and withdrawal of the rejection of claims 20-22, 25 and 32-34.

The rejection of claims 23 and 24 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosure of Francois et al. and Shimizu et al (US 5,824,339) has been reviewed. Applicants' attorney respectfully requests reconsideration and withdrawal of this rejection in view of the following comments.

As previously discussed Francois et al. is considered to be a significant contribution to the art in the formulation of an injectable, aqueous suspensions of 9-hydroxyrisperidone fatty acid esters for depot formulations. However, the present invention is patentably distinguishable from Francois et al.

Shimizu et al. is directed to an effervescent composition comprising a core-shell powder consisting of a fine granular core spray coated with a liquid mixture containing a water-soluble polymer and at least one physiologically active substance and enteric coating film an effervescing component and an auxiliary effervescing agent which provides for controlled release of the physiologically active substance and is useful for preparing a uniform solution or suspension having a refreshing sensation on ingestion. See abstract.

The combination of Francois et al. and Shimizu et al. does not render the present invention obvious. Francois et al. discloses an injectable aqueous suspension depot. Applicants' attorney fails to understand how the teaching of Francois et al. can be combined with Shimizu, which relates to an oral effervescent dosage form. There is nothing in Francois et al or Shimizu to motivate the combination of these two patents with such different delivery means. Accordingly, applicants' attorney submits that because the patents are not properly combinable that a prima facie case of obviousness has not been established and that this rejection should be withdrawn.

Additionally, applicants' attorney wishes to point out that 9-hydroxyrisperidone is an antipsychotic not an antibiotic. Thus, the office action has not linked the relevance of the delivery of the drugs described in Shimizu et al. to the delivery of the antipsychotic compounds described in Francois et al. Applicants' attorney notes that Shimizu et al. does not specifically mention the antipsychotic compounds described in Francois et al.

Further, the combination of these two patents, if proper, does not suggest or disclose the claimed invention, which is a hydrophilic controlled release solid formulation. It is not apparent to the applicants' attorney how the combination of the injectable aqueous suspension depot formulation of Francois et al. and an effervescent composition of Shimizu would provide any motivation to a make a hydrophilic controlled release solid formulation. Accordingly, applicants' attorney respectfully requests reconsideration and withdrawal of the rejection of claims 23 and 24 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosure of Francois et al. and Shimizu et al.

The rejection of claims 26-31 under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Francois et al and Yajima et al. has been considered. However, in view of the following comments applicants attorney respectfully requests reconsideration and withdrawal of this rejection.

As previously discussed Francois et al. is considered to be a significant contribution to the art in the formulation of an injectable aqueous suspensions of 9-hydroxyrisperidone fatty

acid esters for depot formulations. However, the present invention is patentably distinguishable from Francois et al.

Yajima et al is directed to a composition for oral administration comprising an unpleasant tasting drug a high polymer soluble in the stomach and a monglyceride in the β-crystal form. See abstract. Yajima et al. does not disclose the formulation of antibiotic agents in abstract contrary to the statement in the prior office action. Applicants' attorney notes that Yajima does mention the in column 2, line38 et seq. that psychotropic drugs (e.g. chlorpromazine) which is an antipsychotic may be used in Yajima's formulation. However Yajima et al. does not mention or list the antipsychotic compounds described in Francois et al.

Yajima et al is also directed to the formation of taste masking composition in which a monoglyceride is present in the β-crystal form. Yajima does not disclose or describe a hydrophilic controlled release solid formulation comprising 9 hydroxyrisperidone, a pharmaceutically acceptable acid addition salt thereof, an N-oxide form thereof, or a sterochemically isomeric form thereof, and one or more viscous hydrophilic polymers.

The combination of Francois et al with Yajima et al is inappropriate and does not establish a prima facie case of obviousness. As previously mentioned Francois et al. discloses a aqueous suspension. The principle use of the Francois et al depot is for injection into patients in need of treatment. There is no suggestion that the injectable compounds of Francois et al. require taste masking. Similarly Yajima does not disclose or suggest that his formulation would provide a controlled release formulation not the use of the compound of Francois et al to make a hydrophilic controlled release solid formulation containing 9-hydroxyrisperidone. Accordingly, applicants' attorney respectfully requests reconsideration and withdrawal of this rejection.

Regarding the recitation of specific ratios and concentrations and amounts of drug, since the level of skill of one of ordinary skill in this art has not been established, nor have the recited ratios and concentrations or amount of drug been shown in the art to represent routine optimization applicants' attorney submits that until such information provided in some manner that the rejection of the claims on the basis of these general statements is inappropriate. Until

the examiner provides art or a declaration on these points these rejection are not supported by the record and are improper. Consequently applicant requests reconsideration and withdrawal of these rejections.

Applicant respectfully requests that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

By: /Hal Brent Woodrow/
Hal B. Woodrow
Reg. No. 32,501

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2976
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